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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
TEL 781.279.1675
FAX 781.279.1742

May 20, 1999

WARNING LETTER

NWE–25–99W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Hughes de Laforcade
President
Microline, Inc.
800–257–X Cummings Center
Suite 157–X
Beverly, MA 01915

Dear Mr. de Laforcade:

An inspection of your facility located at 800 Cummings Center, Beverly, MA was initiated by Food and Drug Administration (FDA) Inspector Lynne Dwyer on March 17, 1999 and completed on March 24, 1999. This inspection confirmed that your firm manufactures "Re-New II" 5 mm Hybrid Laparascopic Instruments (Handpieces and Tips). This products are medical devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these devices are *adulterated* within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformity with the Quality System Regulation, Title 21, Code of Federal Regulations (CFR), Part 820, promulgated under Section 520(f)(1) of the Act. The following deviations were noted:

- Failure to establish and maintain procedures for the identification, documentation, validation, or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR § 820.30(i). For example:

Your firm's Design Control Procedure, Microline QP 4.04, does not contain a requirement for the validation (or where appropriate, verification) of design changes prior to implementation.

- Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required under 21 CFR § 820.198.

Another device manufactured by your firm, a nondisposable laparoscopic scissor handle, is *misbranded* within the meaning of Section 502(t)(2) of the Act in that your firm failed or refused to furnish any material or information required by or under Section 519 respecting this device. For example:

- Complaint #98001 relates to a patient injury (2nd and 3rd degree burns) which required medical intervention (excising damaged area and suturing the wound). Please refer to 21 CFR § 803.50(a)(1) of the Medical Device Reporting regulation.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter and the Form FDA 483 issued at the close of the inspection may be indicative of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems-related, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices, so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System / Good Manufacturing Practice deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within fifteen (15) working days of the receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to:

Mark Lookabaugh
Compliance Officer
U.S. Food and Drug Administration
One Montvale Avenue, 4th Floor
Stoneham, MA 02180

If you have any questions concerning this matter, please contact Mr. Lookabaugh at ***781.279.1675 x118***.

Sincerely,

John R. Marzilli
Director
New England District